

### **Remarks**

This Amendment is in response to the Office Action dated **March 11, 2008**.

Claims 1-22 are pending in this application. Claims 8 and 9 have been withdrawn from consideration. The Office Action rejected claims 1-4, 10, 13-17 and 22 under 35 USC § 103 over Berra (US 2004/0215319) in view of Khosravi (US 6290720); rejected claims 5-7, 11, 12, 18, 19 and 21 under 35 USC § 103 over Berra in view of Khosravi and Yip (US 2004/0230293); rejected claim 20 under 35 USC § 103 over Berra in view of Khosravi and Yip and further in view of Oepen (US 2002/0161428); and rejected claims 1-4 and 17 under 35 USC § 112, second paragraph.

By this Amendment, claims 23-25 are added. Support for the new claims can be found at least in Figures 7 and 11, and in the specification at page 9, lines 28-31. Reconsideration in view of the above amendments and the following remarks is requested.

### **Claim Rejections - 35 USC § 112**

The Office Action rejects claims 1-4 and 17 under 35 USC § 112, second paragraph, alleging that the claims are indefinite. The rejection asserts that Applicants have not disclosed an embodiment having a combination of straight connecting elements and curved connecting elements, and that the examiner has interpreted the claims as including a second connecting element having a similar shape but different configuration from a first connecting element. See Office Action at pages 2-3. These rejections are traversed.

The claims at issue recite “the second connecting element shaped differently from the first connecting element.” A person of ordinary skill in the art would understand the plain meaning of these limitations, and would understand the scope of these claims.

The application discloses many examples of differently shaped connectors. For example, excerpts from Figures 9 and 12 are provided below, marked to indicate connectors 1, 2 that are shaped differently from one another.

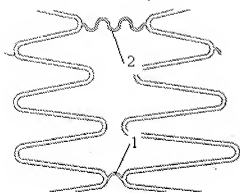


FIG.9

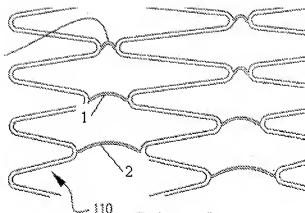


FIG. 12

With respect to the rejection's assertion regarding connectors having a "similar shape but different configuration," Applicants assert that the connectors from either excerpt above do not have a similar shape. The connectors have different shapes – for example, the shape of the first connector cannot be scaled up or down to reach the shape of the second connector. The first connector must be modified in some way, other than a simple scaling, to reach the different shape of the second connector.

With respect to the Office Action's assertion regarding a "combination of straight connecting elements and curved connecting elements" in a single embodiment, the application states, "Any of the inventive features described herein with respect to any of the disclosed embodiments may be selected and combined to form further embodiments of the invention." Therefore, it is within the scope of the original disclosure to combine a straight connecting element from one embodiment with a curved connecting element from another embodiment.

The claim limitations at issue merely require connecting elements that are shaped differently from one another. These limitations are not complex, and their plain meaning clearly conveys the intended claim scope. Therefore, claims 1-4 and 17 are in compliance with the definiteness requirement of 35 USC § 112. Applicants request withdrawal of the rejections under 35 USC § 112.

#### **Claim Rejections – 35 USC § 103**

The Office Action rejected, under 35 USC § 103, claims 1-4, 10, 13-17 and 22 over Berra in view of Khosravi; claims 5-7, 11, 12, 18, 19 and 21 over Berra in view of Khosravi

and Yip; and claim 20 over Berra in view of Khosravi and Yip and further in view of Oepen. These rejections are traversed.

Berra discloses a stent-graft made from a plurality of spaced apart stent springs coupled to a cylindrically shaped stent-graft material. See paragraph 0023. The adjacent stent springs 202 “are spaced apart and coupled, e.g., sewn, to cylindrical shape stent-graft material 203...with sutures (not shown).” See paragraph 0029 (emphasis added) and FIG. 5A, shown below.

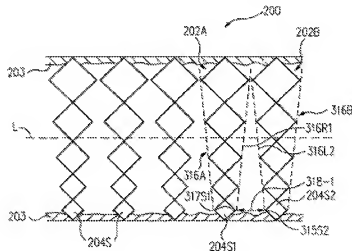


FIG. 5A

The rejection proposes to add connecting elements as taught by Khosravi to the Berra stent-graft, in order to provide an alignment between adjacent bands. See e.g. Office Action at page 4.

Applicants previously argued that a person of ordinary skill in the art would not make the modification proposed in the rejection. The proposed modification is not necessary because the Berra stent springs are coupled to the graft material, which already provides for alignment between adjacent bands. Thus, the proposed modification would not result in an actual benefit over the original Berra device, as Berra’s original device has aligned bands. Further, the additional connecting structure would reduce flexibility of the device, and the resulting modified device would be less desirable than the original Berra device due to the decreased flexibility. Therefore, the rejection has not identified a persuasive reason that would have prompted a person of skill in the art to combine the applied references as proposed, and the rejection has not

presented a *prime facie* case of obviousness.

In response to Applicants' arguments, the Office Action asserts, "Khosravi teaches that the bands may be individually attached to the peripheral wall and/or the bands may be connected to one another by one or more connector elements." See Office Action at page 8. This assertion does not resolve Applicants' argument that the modification to Berra is not necessary. Although individual bands in the Khosravi device could be attached to the graft material, or to one another via connecting elements, the Office Action does not respond to Applicants' assertion that the proposed modification the Berra device would have detrimental effects with no associated benefit.

The Office Action further states, "Khosravi teaches the device is sufficiently flexible to accommodate a tortuous anatomy. Therefore, in contrast to applicant's arguments, Berra's device would still have sufficient flexibility to traverse a tortuous anatomy...." See Office Action at page 8. Although Khosravi teaches that Khosravi's device is sufficiently flexible, the teaching cannot be applied to the modified Berra device proposed in the rejection. Neither Berra nor Khosravi discloses or suggests the modified device proposed in the rejection. Therefore, the modified device is outside the purview of either reference, and neither reference can comment on the flexibility of the modified device. Further, regardless of the flexibility of the modified device, the rejection has not given a valid reason why a person of ordinary skill in the art would add connectors to Berra, when such a modification would likely cause a reduction in flexibility without having any benefit.

Additionally, Khosravi only shows straight connector elements extending between serpentine elements, and teaches that the connector elements preferably extend axially between the serpentine elements. See e.g. Figure 1 and column 4, lines 62-64. There is no teaching in Khosravi that would motivate a person of ordinary skill in the art to use connecting elements that have a different shape, as required by claims 1 and 17, or to use a connecting element that is nonparallel to the stent axis, as required by claim 14. Therefore, Applicants assert that the combination of Berra and Khosravi does not present a *prima facie* case of obviousness against independent claims 1, 14 or 17, or any claims dependent therefrom. Accordingly, Applicants request withdrawal of the rejection of claims 1-4, 10-17, 21 and 22 under 35 USC § 103.

Rejections Applying Yip

The Office Action asserts that Yip teaches bands having turns that meet limitations from the rejected claims, and proposes to modify the Berra stent springs as taught by Yip. See Office Action at pages 6-7. Specifically, the rejection asserts that Figure 37 shows bands having turns in general alignment at only one end of the band, and that varying strut positioning affects flexibility; therefore, it would have been obvious “to try aligning turns at only one end of the band,” as doing so would vary flexibility of the device. See Office Action at pages 6-7.

Applicants assert that a person of ordinary skill in the art would not be motivated to modify the bands of Berra as proposed in the rejection. The proposal requires that a component part of the Yip stent – turn alignment – be dissected and applied to the Berra stent springs; however, the rejection does not cite to any teaching that suggests any benefit would result from such a modification. The rejection merely states that the modification would “vary the flexibility of the device.” See Office Action at page 7. Thus, the rejection does not associate any benefit with the proposed modification – only a change in flexibility. A person of ordinary skill in the art would recognize that the change could be detrimental to the performance of the device. A person of ordinary skill in the art would not be motivated to modify a device unless some benefit was expected as a result. The rejection has not discussed any benefit.

Further, a person of ordinary skill in the art would not modify the Berra stent springs, which have a specific tapered configuration, based upon the mere presence of turn alignment in Yip that, under a hindsight reading, meets limitations from the pending claims.

Yip teaches a generally cylindrical stent, formed from “cylindrical rings.” See e.g. Figures 4 and 37, and paragraphs 0082 and 0101. Figure 37 shows bands wherein some turns are aligned in groups, such as a first group 158 of turns aligned at a first position 160 and a second group of turns 162 aligned at a second position 164. See excerpt from Figure 37 below and paragraph 0101.

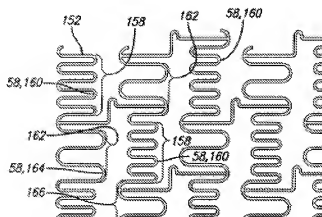


FIG. 37

Yip provides the offset groups of turns to avoid a problem of contact between adjacent bands at the inside of a curve when the stent is subject to curvature along its longitudinal axis. Yip describes the problem of contact as a “train wreck.” See e.g. paragraphs 0007 and 0104. As shown in Figure 37 above, in the Yip stent, the aligned turns that create a wider band (e.g. 162) are aligned with a narrower portion (e.g. 158) of an adjacent band. Thus, the design feature that the rejection focuses upon is intended to prevent “train wrecking.”

The Berra stent springs have a specific tapered shape that allow the Berra device to be placed in curved vessels. See e.g. Figure 5B, provided below.

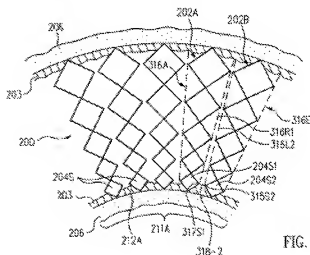


FIG. 5B

A person of ordinary skill in the art would recognize that the Berra stent springs are not subject to a problem of “train wrecking,” as their tapered design inherently prevents the problem. Therefore, a person of ordinary skill in the art would not modify the Berra stent springs to add the offset turns from Yip, either for the train wrecking purpose taught by Yip, or to “vary

flexibility” as asserted in the rejection.

In light of this, the rejection does not articulate a clear reason why a person of ordinary skill in the art would have modified Berra in a way that would result in a stent that meets the limitations of independent claims 5 or 18. Therefore, the rejection has not presented a *prima facie* case of obviousness against claims 5 or 18, or any claims dependent therefrom. The Oepen reference was applied for a teaching of strut thickness, and does not provide any teaching that would motivate a person of skill in the art to modify Berra as required to meet the limitations of independent claims 5 or 18. Accordingly, Applicants request withdrawal of the rejection of claims 5-7 and 18-20 under 35 USC § 103.

#### **New Claims**

New claims are added by this amendment, such as claims 24 and 25, which recite features of connecting elements. At least some of the benefits that result from the configurations described in these claims are discussed in the application at page 9, lines 10-16.

**Conclusion**

Based on at least the foregoing amendments and remarks, Applicants respectfully submit this application is in condition for allowance. Favorable consideration and prompt allowance of claims 1-25 are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in better condition for allowance, the Examiner is invited to contact Applicants' undersigned representative at the telephone number listed below.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

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